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EU DECLARATION OF CONFORMITY

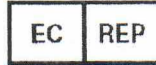
Doc No.: D-MDR-01/08-A01

Identification of the Legal Manufacturer & Address



: Blue Sail Medical Co., Ltd
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,
Zibo, Shandong 255414 China

European Authorized Representative



: Lotus NL B.V.
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands
: Tel: +31 645171879 (English) +31626669008 (Dutch)
: Email: peter@loutsnl.com

Basic UDI-DI

: Details please reference the Article 1.1 part (4) of the CE technical files.

Product & Identification

: **Disposable Vinyl Patient Examination Gloves**

Intended purpose of the product:

The Disposable Vinyl Patient Examination Gloves is a disposable Product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

GMDN code and product:

: **47176 Vinyl examination/treatment glove, non-powdered**
: **47177 Vinyl examination/treatment glove, powdered**
: Detail product code, common specification please reference to Doc#:
D-MDR-01/05-A00, Doc# D-MDR-01/02-A00 in the CE Technical Files.

Risk Classification:

: Class I, Non-sterile, no measuring function and not surgical instrument

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure

: Article 4.1 Rule 1, Non-invasive device, and/or
: Article 5.1 intended for transient use, Rule 5 of invasive device of Annex VIII.

Conformity Route

: Self-Declaration

Relevant Harmonized Standards:

: EN ISO13485:2016
: EN 455-1: 2000, EN455-2:2015, EN455-3 2015, EN455-4:2009
: EN ISO 374-1:2016, EN374-2: 2014, EN16523-1:2015, EN374-4:2013, ENISO 374-5:
2016, EN420: 2003+A1:2009

Certification Body

: TUV SUD PSB Singapore

Registration Date

: 03 Feb 2020

Registration No.

: 04077/04078

Quality System Certificate

: Certificate No: Q5 062837 0012 Rev. 02
: Certificate Body: TUV SUD Product Service GmbH
: Issued Date: 12 Nov 2019

Identification of the person authorized to sign on behalf of the Legal Manufacturer:

: Signed by:

: Print Name: Robin Liu
: Title: Quality Director
: Place of Issue: Zibo, Shandong, China
: Date: 24 Apr 2020